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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,078	06/08/2006	Jianming Chen	601-5	6889
83336 7590 07/06/2010 Kaplan Gilman & Pergament LLP 1480 Route 9 North Woodbridge, NJ 07095				
EXAMINER				
WINTERBERG, NISSA M				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
07/06/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action  
Before the Filing of an Appeal Brief**

**Application No.**

10/563,078

**Applicant(s)**

CHEN ET AL.

**Examiner**

Nissa M. Westerberg

**Art Unit**

1618

***--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

THE REPLY FILED 14 June 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: \_\_\_\_\_.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

/Nissa M Westerberg/  
Examiner, Art Unit 1618

Continuation of 11. does NOT place the application in condition for allowance because: The remarks and declaration are insufficient to overcome the applied rejections.

The maintained rejections are as follows:

Claims 1, 3, 5, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Okada et al. (US 6,455,053). This rejection is maintained for the reasons of record set forth in the Office Actions mailed July 29, 2008, January 30, 2009, July 9, 2009 and March 12, 2010 and those set forth below.

Claims 1, 3, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by DuRoss (US 5,075,291). This rejection is maintained for the reasons of record set forth in the Office Actions mailed July 9, 2009 and March 12, 2010 and those set forth below.

Claims 1 - 3, 6, 7, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (US 6,455,053). This rejection is maintained for the reasons of record set forth in the Office Actions mailed July 29, 2008, January 29, 2009, July 9, 2009 and March 12, 2010 and those set forth below.

Claims 1 - 3, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over DuRoss (US 5,075,291) in view of Okada et al. (US 6,455,053). This rejection is maintained for the reasons of record set forth in the Office Actions mailed July 9, 2009 and March 12, 2010 and those set forth below.

Applicants arguments regarding the Abbott Labs decision and product-by-process limitation in regards to validity and infringement were addressed in the March 12, 2010 Office Action and the new arguments are unpersuasive to determine that the decision should apply to the examination of applications before the Patent and Trademark Office. Such a determination does not require disclosure of the cited prior art of the process steps in a product-by-process claim.

Applicants submit an additional declaration by Chen Jianming that states the ingredients present in the comparisons made and the data reported in the January 11, 2010 declaration, also by Chen Jianming. Even with this information, the evidence remains not commensurate in scope with the claims and is therefore not found to be persuasive. The drop pill methodology used to prepare the drop pills in accordance with the instant invention is much narrower than any of the product-by-process limitations found in the claims - utilizing specific amounts of the recited ingredients and a particular coolant at 4 C. Based on the comparison performed, only two different matrix adjuvants were tested and these were both sugar alcohols. These compositions compare one example from each of the applied references - Okada and DuRoss - and utilize one pharmaceutical active ingredient. The Markush group of possible matrix adjuvants encompasses a wide variety of sugars, sugar alcohols and even carboxylic acid compounds. As the claims contain no limitations on the amounts of the various ingredients present and the variety of possible matrix adjuvants, the evidence in the declarations is not commensurate in scope with the claims. Additionally, for product-by-process claims, Applicants must not only show that the products are different but also that the products are non-obvious. Applicants have not met the burden to show that full breadth of the instant product claims are patentable over the applied cited prior art and the above rejections are maintained.